STATUTORY INSTRUMENTS

2006 No. 552

The National Health Service (Local Pharmaceutical Services etc.) Regulations 2006

PART 1

GENERAL

Citation, commencement and application

1.—(1) These Regulations may be cited as the National Health Service (Local Pharmaceutical Services etc.) Regulations 2006 and shall come into force on 1st April 2006.

(2) These Regulations apply in relation to England only(1).

Interpretation

2.—(1) In these Regulations—

"the 1990 Act" means the National Health Service and Community Care Act 1990(2);

"the Abolition of the Tribunal Regulations" means the Abolition of the National Health Service Tribunal (Consequential Provisions) Regulations 2001(**3**);

"the Act" means the National Health Service Act 1977;

"advanced electronic signature" means an electronic signature which is-

- (a) uniquely linked to the signatory;
- (b) capable of identifying the signatory;
- (c) created using means that the signatory can maintain under his sole control; and
- (d) linked to the data to which it relates in such a manner that any subsequent change of data is detectable;

"appliance" means an appliance which is included in a list for the time being approved by the Secretary of State for the purposes of section 41 of the Act (arrangements for pharmaceutical services);

"appropriate non-proprietary name" means a non-proprietary name which is not mentioned in Schedule 1 to the Prescription of Drugs Regulations (drugs, medicines and other substances not to be ordered under a general medical services contract) or, except where the conditions in paragraph 42(2) of Schedule 6 to the GMS Contracts Regulations are satisfied, in Schedule 2 to the Prescription of Drugs Regulations (drugs, medicines and other substances that may be ordered only in certain circumstances);

As regards Wales, the relevant functions of the Secretary of State under the Act were transferred to the National Assembly for Wales under S.I. 1999/672, read with section 68(1) of the 2001 Act.

⁽**2**) 1990 c. 19.

⁽**3**) S.I. 2001/3744.

"associated batch issue" means, in relation to a non-electronic repeatable prescription, one of the batch issues relating to that prescription and containing the same date as that prescription;

"batch issue" means a form provided by a Primary Care Trust and issued by a repeatable prescriber at the same time as a non-electronic repeatable prescription which enables a contractor to receive payment for the provision of repeat dispensing services, which is in the format required by the NHS Business Services Authority, and which—

- (a) is generated by a computer and not signed by a repeatable prescriber;
- (b) relates to a particular non-electronic repeatable prescription and contains the same date as that prescription;
- (c) is issued as one of a sequence of forms, the number of which is equal to the number of occasions on which the drugs or appliances ordered on the non-electronic repeatable prescription may be provided; and
- (d) specifies a number denoting its place in the sequence referred to in sub-paragraph (c);

"the Charges Regulations" means the National Health Service (Charges for Drugs and Appliances) Regulations 2000(4);

"chemical reagent" means a chemical reagent included in a list for the time being approved by the Secretary of State for the purposes of section 41 of the Act(5);

"contractor" means the party or parties to an LPS scheme which is or are not the Primary Care Trust;

"dentist" means a dentist registered in the dentists register maintained under section 14 of the Dentists Act 1984(6);

"doctor" means a registered medical practitioner;

"drugs" includes medicines;

"Drug Tariff" means the statement compiled and published under regulation 56(1) of the Pharmaceutical Services Regulations (standards of, and payments for, drugs and appliances);

"electronic communication" has the meaning given in section 15 of the Electronic Communications Act 2000(7) (general interpretation);

"electronic prescription" means an electronic prescription form or an electronic repeatable prescription;

"electronic prescription form" means a prescription which falls within (b) of the definition of "prescription form";

"electronic repeatable prescription" means a prescription which falls within paragraph (a)(ii) of the definition of "repeatable prescription";

"ETP service" means the electronic prescription service which forms part of the NHS Care Record Service;

"equivalent body" means—

- (a) a Local Health Board in Wales or, in relation to any time prior to 1st April 2003, a Health Authority in Wales;
- (b) a Health Board or NHS trust in Scotland;
- (c) a Health and Social Services Board in Northern Ireland; or

⁽⁴⁾ S.I. 2000/620; as amended by S.I. 2000/2393 and 3189, 2001/746 and 2887, 2002/548 and 2352, 2003/699 and 1084, 2004/663, 696, 865 and 1771, and 2005/578 and 641.

⁽⁵⁾ Section 41 was substituted by the 2001 Act, section 41, and amended by the 2002 Act, Schedule 2, paragraph 13, and by S.I. 2003/1590 and 2004/1771.

^{(6) 1984} c. 24.

^{(7) 2000} c. 7.

(d) in relation to any time prior to 1st October 2002, a Health Authority in England;

"FHSAA" means the Family Health Services Appeal Authority constituted under section 49S of the Act(8) (the Family Health Services Appeal Authority);

"the GMS Contracts Regulations" means the National Health Service (General Medical Services Contracts) Regulations 2004(9);

"Health and Social Services Board" means a Health and Social Services Board established under the Health and Personal Social Services (Northern Ireland) Order 1972(10);

"Health Board" means a Health Board established under section 2 of the National Health Service (Scotland) Act 1978(11) (Health Boards);

"independent nurse prescriber" means a person-

- (a) who is registered in the Nursing and Midwifery Register; and
- (b) in respect of whom is recorded in that register an annotation signifying that he is qualified to order drugs and appliances—
 - (i) until 30th April 2006, from the Nurse Prescribers' Formulary for District Nurses and Health Visitors in Part XVIIB(i) of the Drug Tariff,
 - (ii) until 30th April 2006, from the Nurse Prescribers' Extended Formulary in Part XVIIB(ii) of the Drug Tariff,
 - (iii) as an independent nurse prescriber, or
 - (iv) as a community practitioner nurse prescriber;

"licensing or regulatory body" means a body that licenses or regulates any profession of which a person is or has been a member, and includes any body which licenses or regulates such a profession in a country other than the United Kingdom;

"listed appliance" means an appliance which is listed from time to time in Parts IXA, IXB, IXC or X of the Drug Tariff;

"Local Medical Committee" means a committee recognised under section 45A of the Act(12) (Local Medical Committees);

"Local Pharmaceutical Committee" means a committee recognised under section 44(B2)(b) of the Act(13) (which relates to recognition of Local Pharmaceutical Committees);

"national disqualification" means-

- (a) a decision made by the FHSAA under section 49N of the Act(14) (national disqualification) in relation to a person who has been removed from a pharmaceutical list;
- (b) a decision under provisions in force in Scotland or Northern Ireland corresponding to section 49N of the Act; or
- (c) a decision by the Tribunal which is treated as a national disqualification by the FHSAA by virtue of regulation 4 of the Abolition of the Tribunal Regulations;

"National Health Service Counter Fraud and Security Management Service" means the Special Health Authority of that name with responsibility for policy and operational matters relating to the prevention, detection and investigation of fraud or corruption and the management of

⁽⁸⁾ Section 49S was inserted by the 2001 Act, section 27(8)(b), and amended by the 2002 Act, Schedule 1, paragraph 18.

⁽⁹⁾ S.I. 2004/291; amended by S.I. 2004/2694 and 2005/893 and 3315.

⁽¹⁰⁾ S.I. 1972/1265 (N.I. 14).

^{(11) 1978} c. 29.

⁽¹²⁾ Section 45A was inserted by the 2003 Act, Schedule 11, paragraph 23.

⁽¹³⁾ Subsection (B2) was inserted into section 44 by the 2002 Act, section 5(4), and subsection (B2)(b) was inserted by S.I. 2002/2861 and applies with the modifications set out in paragraph 6 of Schedule 1 to these Regulations.

⁽¹⁴⁾ Section 49N was inserted by the 2001 Act, section 25, and amended by the 2002 Act, Schedule 2, paragraph 25.

security in the National Health Service, which was replaced on 1st April 2006 by the NHS Business Services Authority;

"NHS Business Services Authority" means the NHS Business Services Authority (Awdurdod Gwasanaethau Busnes y GIG) established by the NHS Business Services Authority (Awdurdod Gwasanaethau Busnes y GIG) (Establishment and Constitution) Order 2005(15);

"NHS Care Record" means the records relating to an individual patient held by the NHS Care Record Service;

"NHS Care Record Service" means information technology systems procured by the Department of Health and used by the health service to hold medical records relating to patients;

"NHS dispute resolution procedure" means the procedure for disputes specified in Schedule 2, paragraph 22;

"nominated dispensing contractor" means-

- (a) a contractor;
- (b) a person included in a pharmaceutical list;
- (c) a party to a general medical services contract other than a Primary Care Trust; or
- (d) a party to section 28C arrangements other than a Primary Care Trust or a Strategic Health Authority,

whom a patient has nominated in his NHS Care Record to dispense his electronic prescriptions;

"non-electronic repeatable prescription" has the same meaning as in the Pharmaceutical Services Regulations;

"non-proprietary name", in relation to a drug, means-

- (a) where—
 - (i) the drug is described in a monograph in the current edition, as defined in section 103(5) of the Medicines Act 1968(16) (construction of references to specified publications), as in force at the time of the supply of the drug, of the European Pharmacopoeia, the British Pharmacopoeia, the British Pharmaceutical Codex, the British National Formulary, the International Pharmacopoeia, the Cumulative List of Recommended International Non-proprietary Names or the Dental Practitioners' Formulary, any name, or abbreviation of the name, at the head of that monograph, or
 - (ii) if that name consists of two or more words, any name derived from a suitable inversion of such words which is permitted by that publication; or
- (b) where the drug is not so described in a monograph, but has an approved name, being the name which appears in the current edition, as defined in section 103(5) of the Medicines Act 1968, of the list of names prepared and published under section 100 of that Act (lists of names), as in force at the time of the supply of the drug, its approved name;

"Nursing and Midwifery Register" means the register maintained by the Nursing and Midwifery Council under article 5 of the Nursing and Midwifery Order 2001(17);

"Patients' Forum" means a body established under section 15(1) of the National Health Service Reform and Health Care Professions Act 2002 (establishment of Patients' forums);

⁽**15**) S.I. 2005/2414.

^{(16) 1968} c. 67. Section 103(5) was amended by the Health and Medicines Act 1988 (c. 49), section 22(6), and modified by S.I. 1994/3144.

⁽¹⁷⁾ S.I. 2002/253; there are no relevant amending instruments.

"Pharmaceutical Services Regulations" means the National Health Service (Pharmaceutical Services) Regulations 2005(18);

"pharmaceutical list" shall be construed in accordance with regulation 4 of the Pharmaceutical Services Regulations (pharmaceutical lists);

"pharmacist independent prescriber" means a person-

- (a) who is registered in the Register of Pharmaceutical Chemists maintained in pursuance of section 2(1) of the Pharmacy Act 1954(19) or the register maintained in pursuance of Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976(20); and
- (b) against whose name in that register is recorded an annotation signifying that he is qualified to order drugs, medicines and appliances as a pharmacist independent prescriber;

"prescriber" means a doctor, a dentist, an independent nurse prescriber, a pharmacist independent prescriber or a supplementary prescriber;

"prescription form" means-

- (a) a form provided by a Health Board, a Health and Social Services Board, a Local Health Board, a Primary Care Trust, an NHS Trust or an NHS Foundation Trust, and issued by a prescriber; or
- (b) data that are created in an electronic form, signed with a prescriber's advanced electronic signature and transmitted as an electronic communication to a nominated dispensing contractor by the ETP service,

to enable a person to obtain pharmaceutical services or local pharmaceutical services, and does not include a repeatable prescription;

"Prescription of Drugs Regulations" means the National Health Service (General Medical Services)(Prescription of Drugs etc.) Regulations 2004(21);

"primary care list" means-

- (a) a list of persons performing primary medical or dental services under section 28X of the Act(22) (persons performing primary medical and dental services);
- (b) a list of persons undertaking to provide general ophthalmic services or, as the case may be, pharmaceutical services prepared in accordance with regulations made under section 39, 42 or 43 of the Act(23) (which relate to regulations as to ophthalmic services, pharmaceutical services and persons authorised to provide pharmaceutical services);
- (c) a list of persons who undertook to provide general medical services or general dental services prepared in accordance with regulations made under section 29 or 35 of the Act(24) (which related to regulations as to general medical services and general dental services);

^{(18) 2005/641;} amended by S.I. 2005/1015, 1501 and 3315.

⁽**19**) 1954 c. 61.

⁽²⁰⁾ S.I. 1976/1213 (N.I. 22).

⁽²¹⁾ S.I. 2004/629, as amended by S.I. 2004/3215.

⁽²²⁾ Section 28X was inserted into the Act by the 2003 Act, section 179(1).

⁽²³⁾ Section 39 has been amended by: the Health Services Act 1980 (c. 53) ("the 1980 Act"), sections 1 and 2 and Schedule 1, paragraph 51; the Health and Social Security Act 1984 (c. 48), sections 1 and 24 and Schedule 9; the 1999 Act, section 9; the 2001 Act, section 20; and the 2002 Act, Schedule 2, paragraph 12. Section 42 has been amended by: the National Health Service (Amendment) Act 1986 (c. 66), section 3; the Health Authorities Act 1995 (c. 17) ("the 1995 Act"), Schedule 1, paragraph 30; the 2001 Act, sections 20, 23, 43 and 67, and Schedule 6; and the 2002 Act, Schedule 2, paragraph 16. Section 43 has been amended by the 1980 Act, section 21; the 1990 Act, Schedule 9, paragraph 18; the 1995 Act, Schedule 1, paragraph 31; the 1997 Act, sections 29 and 41 and Schedule 2, paragraph 14; the 2001 Act, section 20; the 2002 Act, sections 2 and 42 and Schedule 2, paragraph 17; and the 2003 Act, Schedule 11, paragraph 19.

⁽²⁴⁾ Sections 29 and 36 were repealed by the 2003 Act, sections 175(2) and 196, and Schedule 14, Part 4.

- (d) a list of persons approved for the purposes of assisting in the provision of any services mentioned in paragraph (b) or (c) prepared in accordance with regulations made under section 43D of the Act(25) (supplementary lists);
- (e) a services list that fell within the meaning of section 8ZA of the National Health Service (Primary Care) Act 1977(26) (lists of persons who may perform personal medical services or personal dental services);
- (f) a list corresponding to a services list prepared by virtue of regulations made under section 41 of the Health and Social Care Act 2001(27) (corresponding provision and application of enactments); or
- (g) a list corresponding to any of the above lists in Scotland or Northern Ireland;

"professional conduct" includes matters relating both to professional conduct and professional performance;

"relevant scheme" shall be construed in accordance with regulation 4(3);

"relevant home Primary Care Trust" shall, as the context requires, be construed in accordance with regulation 17(5) or paragraph 17(2) of Schedule 2;

"Remission of Charges Regulations" means the National Health Service (Travel Expenses and Remission of Charges) Regulations 2003(**28**);

"repeat dispensing services" means local pharmaceutical services which involve the provision of drugs or appliances by a contractor in accordance with a repeatable prescription;

"repeatable prescriber" has the same meaning as in the Pharmaceutical Services Regulations;

"repeatable prescription" means a prescription which—

- (a) either—
 - (i) is contained in a form provided by a Primary Care Trust and issued by a repeatable prescriber which is in the format required by the NHS Business Services Authority, and which is generated by a computer and signed in ink by a repeatable prescriber, or
 - (ii) consists of data that are created in an electronic form, signed with a repeatable prescriber's advanced electronic signature and transmitted as an electronic communication to a nominated dispensing contractor by the ETP service;
- (b) is issued or created to enable a person to obtain pharmaceutical services or local pharmaceutical services; and
- (c) indicates that the drugs or appliances ordered on that prescription may be provided more than once, and specifies the number of occasions on which they may be provided;

"restricted availability appliance" means an appliance which is approved for particular categories of person or particular purposes only;

"Scheduled drug" means a drug or other substance specified in-

- (a) Schedule 1 to the Prescription of Drugs Regulations; or
- (b) except where the conditions in paragraph 42(2) of Schedule 6 to the GMS Contracts Regulations are satisfied, Schedule 2 to the Prescription of Drugs Regulations.

"superintendent" has the same meaning as it has in section 71 of the Medicines Act 1968 (bodies corporate);

⁽²⁵⁾ Section 43D was inserted into the Act by section 24 of the 2001 Act.

^{(26) 1997} c. 46. Section 8ZA was inserted by the 2001 Act, section 26(2), and repealed by the 2003 Act, section 196 and Schedule 14, Part 4.

^{(27) 2001} c. 15.

⁽²⁸⁾ S.I. 2003/2382, as amended by S.I. 2004/663 and 936.

"supplementary prescriber" means a person-

- (a) whose name is registered in—
 - (i) the Nursing and Midwifery Register,
 - (ii) the Register of Pharmaceutical Chemists maintained in pursuance of section 2(1) of the Pharmacy Act 1954,
 - (iii) the register maintained in pursuance of Articles 6 and 9 of the Pharmacy (Northern Ireland) Order 1976,
 - (iv) the part of the register maintained by the Health Professions Council in pursuance of article 5 of the Health Professions Order 2001(29) relating to—
 - (aa) chiropodists and podiatrists,
 - (bb) physiotherapists, or
 - (cc) diagnostic or therapeutic radiographers, or
 - (v) the register of optometrists maintained by the General Optical Council in pursuance of section 7 of the Opticians Act 1989(30); and
- (b) against whose name is recorded in the relevant register an annotation signifying that he is qualified to order drugs and appliances as a supplementary prescriber;

"suspended" means-

- (a) suspended by a Primary Care Trust or equivalent body under
 - (i) sections 49I (suspension) or 49J (suspension pending appeal) of the Act(31),
 - (ii) regulations made under section 28DA (lists of persons who may perform personal medical services or personal dental services)(32) or 43D of the Act (supplementary lists) of the Act, or
 - (iii) section 8ZA (lists of persons who may perform personal medical services or personal dental services) of the National Health Service (Primary Care) Act 1977; or
- (b) in relation to Scotland or Northern Ireland, suspended under provisions in force corresponding to those in or made under sections 28DA, 43D, 49I or 49J of the Act or under section 8ZA of the National Health Service (Primary Care) Act 1977,

and shall be treated as including a case where a person is treated as suspended by a Primary Care Trust or, prior to 1st October 2002, by a Health Authority by virtue of regulation 6(2) of the Abolition of the Tribunal Regulations, or, in Wales, by a Local Health Board, or prior to 1st April 2003, by a Health Authority by virtue of regulation 6(2) of the Abolition of the National Health Service Tribunal (Consequential Provisions) Regulations 2002(**33**), and "suspends" and "suspension" shall be construed accordingly; and

"Tribunal" means the Tribunal constituted under section 46 of the Act(**34**) (the NHS tribunal) for England and Wales, and which, except for prescribed cases, had effect in relation to England only until 14th December 2001, and in relation to Wales only until 26th August 2002(**35**).

⁽²⁹⁾ S.I. 2002/254; there are no relevant amending instruments.

⁽**30**) 1989 (c. 44).

⁽³¹⁾ Sections 49I and 49J were inserted by the 2001 Act, section 25, and were amended by the 2002 Act, Schedule 2, paragraphs 21 and 22.

⁽³²⁾ Section 28DA was inserted into the Act by the 2001 Act, section 26(1), and repealed by the 2003 Act, Schedule 14, Part 4, in relation to personal medical services.

⁽³³⁾ S.I. 2002/1920. These Regulations apply in relation to Wales only.

⁽³⁴⁾ Section 46 was substituted by the 1999 Act, section 40(1), and repealed by the 2001 Act, section 16.

⁽³⁵⁾ See S.I. 2001/3738, article 2(5) and (6)(b), which sets out the prescribed cases for England, and S.I. 2002/1919, article 2(2) and (3)(b), which sets out the prescribed cases for Wales.

(2) In these Regulations, "local pharmaceutical services" means services of a kind which may be provided under section 41 of the 1977 Act(36) (arrangements for pharmaceutical services), or by virtue of section 41A of that Act(37) (arrangements for providing additional pharmaceutical services), other than practitioner dispensing services.

Application of provisions of the Act and the Health Service Commissioners Act 1993 with modifications

3. Schedule 1 shall have effect (which applies with modifications provisions of the Act and the Health Service Commissioners Act 1993(**38**) and makes an amendment to the Act).

(38) 1993 c. 46.

⁽³⁶⁾ Section 41 was substituted by the 2001 Act, section 42(1), and was amended by the 2002 Act, Schedule 2, paragraphs 13(1) to (3), the 2003 Act, Schedule 11, paragraph 18(1) and (2), and by S.I. 2003/1590 and 2004/1771.

⁽³⁷⁾ Section 41A was inserted by the 1997 Act, section 27, and amended by the 2001 Act, section 43(1).